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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,820	06/27/2003	Boris Zavizion	V0191.70030US00	7999

7590 02/10/2005

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EXAMINER	
MINNIFIELD, NITA M	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 02/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/608,820	ZAVIZION ET AL.	
	Examiner	Art Unit	
	N. M. Minnifield	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,9-19 and 31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,9-19 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892) 2 sheets

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/10/05*. 7 sheets

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicants' amendment filed November 12, 2004 is acknowledged and has been entered. Claims 7, 8, 20-30 and 32-34 have been canceled. Claims 1, 2, 6, 10, 12, 17, 18 and 31 have been amended. Claims 1-6, 9-19 and 31 are now pending in the present application. All rejections/objections have been withdrawn in view of Applicants' amendment to the claims and/or comments with the exception of those discussed below.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Applicants' claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the CIP application, 08/521,245, now U.S. Patent 6,114,108 upon which priority of 8/29/95 is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 9-11 and 14-15 of this application. For purposes of prior art examination, the priority date of 8/29/95 will be used for claims 1-8, 12-13, 16-19, and 31, and the priority date of 5/13/97 will be used for claims 9-11 and 14-15.

In the remarks of the paper filed November 12, 2004, Applicants have asserted that the August 29, 1995 priority document discloses species, which fall within the formula of currently pending claims 9 and 11. However, Applicants have not pointed to specific pages/lines or figures in the specification of application 08/521245 where support can be found for claims 9 and 11 to have an

effective filing date of 8/29/95. Therefore, for claims 9-11 and 14-15 the priority date is 5/13/97.

4. Claims 1-6 and 8-12 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of copending U.S. Application No. 10/406,875 now U.S. PreGrant Publication 2003/0202986. Although the conflicting claims are not identical, they are not patentably distinct from each other because both methods appear to function the same by inactivating DNA replication through modifying nucleic acids molecules using aziridino compounds in infectious entities containing a transforming DNA fragment that are found within the same biological compositions.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

This rejection is withdrawn because Applicants have canceled claims 1-11 of co-pending US Application 10/406875. The pending claims in 10/406875 are directed to a device.

5. Claims 1-6 and 9-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,093,564. Although the conflicting claims are not identical, they are not patentably distinct from each other because both methods appear to function the same by selectively inactivating DNA replication through modifying nucleic acids molecules using aziridino compounds in infectious entities containing a

transforming DNA fragment that are found within the same biological compositions.

6. Claims 1-6 and 9-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,352,695. Although the conflicting claims are not identical, they are not patentably distinct from each other because both methods appear to function the same by selectively inactivating DNA replication through modifying nucleic acids molecules using aziridino compounds in infectious entities containing a transforming DNA fragment that are found within the same biological compositions.

7. Claims 1-4, 14, 17, 19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 7-10 of U.S. Application 09/877,838 now U.S. PreGrant Publication 2002/0034724. Although the conflicting claims are not identical, they are not patentably distinct from each other because both methods appear to function the same by inactivating bacteria using aziridino compounds that are found within the same biological compositions.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. The rejections set forth in above paragraphs 5-7 are maintained for the reasons of record. Applicants' arguments filed November 12, 2204 have been fully considered but they are not persuasive. Applicants have asserted that claim 1

has been amended to add the limitation of claim 7, which was not rejected in view of 6,093,564 or 6352695 or 09/877838. And in view of the pending claims, claims 1-6 and 9-12 are therefore patentable in view of 6,093,564 or 6352695 or 09/877838. However, the limitation of canceled claim 7 recites that the biological composition is derived from humans. Claims 9 and 10 found in issued patents 6093564 and 6352695 respectively recite that the biological composition is selected from the group consisting of mammalian blood for example. A human is a mammalian and therefore the biological compositions of the issued patents can be derived from humans. With regard to application 09/877838, the pending claims recite mammalian cells as well as the mammal being a human; therefore the biological composition is derived from humans.

9. Claims 2-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding the claims, the phrase "e.g." which means "for example" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

10. Claims 1-6, 9-19 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wollowitz et al (5691132) and Pierce (3487157) taken with Kostyanovskii et al 1989 (Bull. Acad. Sci. USSR, 1989, 37:2315-2325) or Tanirbergenov et al 1988 (Genetika, April 1988, 24/4:763-765).

Wollowitz et al teaches a method of eliminating transmission of diseases through blood products by a means of inactivating the pathogens in transfusion

products (i.e. inactivating a parasite in a biological composition) (col. 2; col. 9-10; claims; cols. 13-14). Wollowitz et al teaches "methods for the in vitro inactivation of pathogens in biological materials intended for in vitro or in vivo use, and in particular the inactivation of pathogens in solutions containing red blood cells, prior to clinical testing or transfusion. In accordance with the present invention, a compound having a nucleic acid binding ligand and a mustard group is selectively employed to treat contamination by nucleic acid-containing microorganisms, including pathogenic viruses. Without intending to suggest a mechanism for the present invention such compounds are alkylating agents." (col. 3, l. 16-35). The mustard group is a aziridino (i.e. ethyleneimine) compound and Wollowitz et al teaches that the mustard groups complex with nucleic acids to form complexes, which inhibit nucleic acid replication (col. 6). The prior art contemplates the inactivation of both viral and bacterial pathogens that are in biological samples (col. 3). Wollowitz et al teaches methods of inactivating pathogens in blood products (col. 4). Wollowitz et al teaches methods of inactivating pathogens present in blood products through a single procedure and it has the potential to eliminate bacteria, protozoa (i.e. parasites), and viruses (col. 11). Pierce teaches an aziridine with a straight alkyl, that it is an antimicrobic agent, as well as methods of inactivating microorganism (col. 2; claims). Wollowitz et al and Pierce teach the claimed invention except for the aziridino compound being an ethyleneimine oligomer, ethyleneimine dimmer or ethyleneimine trimer.

However, both Kostyanovskii et al (see page 2315, first paragraph) and Tanirbergenov et al (see the English Translation, page 1, second paragraph, and page 4, second from last sentence) teach inactivation of bacterial cells and microorganisms with ethyleneimine oligomers. They both teach that monomers,

dimers and trimers can be used for inactivation. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine the teachings of Wollowitz et al and Pierce with Kostyanovskii et al or Tanirbergenov et al to use the inactivating compounds taught in each of the references to inactivate microorganism found in biological compositions. Microorganisms are viewed as encompassing pathogens, bacteria, viruses, parasites, etc. Further, it would have been obvious to one of ordinary skill in the art to use the ethyleneimine oligomers, dimers or trimers to activate the microorganisms since Tanirbergenov et al teaches that the maximal induction factor increases from monomer to trimer (see Table). Both Wollowitz et al and Pierce teach that the biological composition can be blood products derived from mammals (i.e. humans). With regard to the concentration of inactivating agent (ethyleneimine oligomer) preparation used in the method, such limitations would have been obvious to one of skill in the art as a routine optimization of the method. The claimed invention is prima facie obvious in view of the combined teachings of the prior art, absent any convincing evidence to the contrary.

11. No claims are allowed.

12. The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

14. The information disclosure statement filed January 10, 2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Please note, cited prior applications (09/877838 and 09609687) have been reviewed for cited references on the January 10, 2005 IDS. Prior applications, 09161303and 08855378, are not available to the Examiner. The Examiner has considered and initialed the references that could be obtained. A copy of those references not initialed should be provided for consideration.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

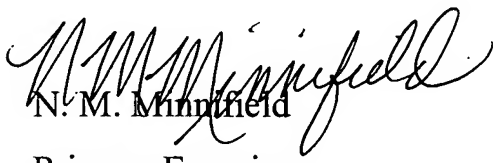
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will

be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



N. M. Minnifield
Primary Examiner
Art Unit 1645

NMM
February 3, 2005